UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NEW ENGLAND REGION
5 POST OFFICE SQUARE SUITE 100 OES 05-1 BOSTON, MA 02109-3912

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JUN 0 8 2017

Damon D'Amico, President
Alden Medical, LLC
360 Cold Spring Avenue, Suite 1
West Springfield, MA 01089

Re: Notice of Noncompliance Regarding the Chemical Accident Prevention Requirements of the Clean Air Act for Alden Medical, LLC in West Springfield, Massachusetts

Dear Mr. D'Amico:

On August 11, 2014, representatives of the United States Environmental Protection Agency ("EPA") conducted an inspection of the Alden Medical, LLC facility in West Springfield, Massachusetts. The purpose of the inspection was to determine Alden Medical's compliance with the chemical accident prevention and mitigation requirements of Section 112(r)(1) of the Clean Air Act ("CAA"), 42 U.S.C. § 7412(r)(1), otherwise known as the General Duty Clause, and with Section 312 of the Emergency Planning and Community Right-to-Know Act ("EPCRA"), 42 U.S.C. § 11022.

Pursuant to Section 312 of EPCRA and the Hazardous Chemical Reporting: Community Right-to-Know Rule, 40 C.F.R. Part 370, any facility that is required to prepare, or have available, a material safety data sheet ("MSDS") for a hazardous chemical under the Occupational Safety and Health Act of 1970 and regulations promulgated thereunder must prepare and submit an emergency and hazardous chemical inventory form ("Inventory Form") to the local emergency planning committee ("LEPC"), the state emergency response commission ("SERC"), and the local fire department. Pursuant to 40 C.F.R. §§ 370.40 and 370.45, the Inventory Form must be submitted annually on or before March 1st and is required to contain information with respect to the preceding calendar year.

Based upon EPA's inspection of your facility on August 11, 2014, and a review of other information, EPA has determined that Alden Medical failed to submit an accurate Inventory Form for reporting year 2013. The Inventory Form that Alden Medical originally submitted for reporting year 2013 listed only hydrogen peroxide and propylene glycol. However, after EPA's visit, Alden Medical re-examined its information and submitted a revised Inventory Form for reporting year 2013 ("RY13") and a new form for reporting year 2014 ("RY14") that identified

many more chemicals at the facility in excess of the reporting thresholds.[1] Additionally, the quantities of certain chemicals on the Inventory Forms for RY13 (both the original and revised) and RY14 were inconsistent with and less than EPA's observations and estimates, including for the "extremely hazardous substance" paracetic acid. It appears that Alden is not correctly accounting for all the chemical components of the various mixtures at the Facility.[2] These inaccuracies represent a violation of Section 312 of EPCRA, 42 U.S.C. § 11022.

Pursuant to the General Duty Clause, owners and operators of stationary sources producing, processing, handling, or storing substances listed pursuant to Section 112(r)(3) of the CAA, 42 U.S.C. § 7412(r)(3), or any other extremely hazardous substance, have a general duty, in the same manner and to the same extent as 29 U.S.C. § 654, to (a) identify hazards which may result from accidental release of substances using appropriate hazard assessment techniques; (b) design and maintain a safe facility taking such steps as are necessary to prevent releases; and (c) minimize the consequences of accidental releases which do occur.

Based upon EPA's inspection of your facility on August 11, 2014, and a review of other information, EPA has determined that Alden Medical failed to design and maintain a safe facility, taking such steps as are necessary to prevent releases, as required by the General Duty Clause, including as detailed below.

- The following compressed gas cylinders were improper stored:
    - The empty cylinder location in the Production, Quarantine, and Shipping Area was immediately adjacent to an electrical breaker box and outlet, which is not in accordance with Compressed Gas Assoc., "Pamphlet P-1: Safe Handling of Compressed Gases in Containers" § 5.4 (2008) [hereinafter "CGA Pamphlet P-1"] (containers should not be placed where they can become part of an electrical circuit);
    - One cylinder in the empty storage location of the Production, Quarantine, and Shipping Area was tagged as full and two cylinders lacked tags indicating whether they were empty or full, which is not in accordance with CGA Pamphlet P-1 § 5.8.2 (separate storage of full and empty containers);

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[1] Including: acetic acid – glacial, Alcalase 2.5L, Aldahol (3.96% glutaraldehyde + 23.47% isopropyl alcohol), Compliance (0.239% peracetic acid + 7.13% hydrogen peroxide), Empower, FMC hydrogen peroxide, glutaraldehyde, hydrogen peroxide (35% to 52% by weight), isopropyl alcohol, Metricide OPA Plus (0.65% ortho-phthalaldehyde), ortho-phthalaldehyde, peracetic acid, Peracidin/Peraldecide (5% peracetic acid + 28% hydrogen peroxide), potassium acetate, propylene glycol, and sodium citrate.

[2] For example, the original and revised RY13 Inventory Forms as well as the RY14 Inventory Form listed the maximum amount of hydrogen peroxide in inventory as 10,850 pounds, while also listing the maximum shipment quantity as 31,000. Further, EPA estimates, based on observation and information stemming from the inspection, that the quantity on-site may be closer to 49,768 pounds. Similarly, in its RY13 and RY14 Inventory Forms, Alden Medical reported 13,000 pounds of propylene glycol while EPA estimates the total to be 62,370 pounds. Additionally, in its RY14 Inventory Form, Alden Medical listed only 2,082 pounds of Peracidin, which is significantly lower than the EPA-estimated 65,939 pounds of this mixture. These inconsistencies and discrepancies may be due to Alden Medical variously reporting the amount of "pure" chemical and the amount contained in mixture throughout the entire Facility. Tier II reporting requires consistently reporting *either* the mixture or constituent totals throughout a facility's submission.

- Full hydrogen and oxygen cylinders were next to each other in the Production, Quarantine, and Shipping Area, which was not in accordance with CGA Pamphlet P-1 (2008) §§ 5.8.2 (spacing or segregation by partition and grouping containers by hazard class); 6.2.1 (flammable gases should be stored apart from oxiders); 6.4.3 (oxiders should be store separately from flammable gas containers);
- The propane cylinders for the forklift were not safely stored in the Production, Quarantine, and Shipping Area, in that some extended beyond the rack space into an access way and they were not secured or properly nested, which is not in accordance with CGA Pamphlet P-1 §§ 5.8.2 (containers should not be stored near walkways or other locations where heavy moving objects could strike them); 5.8.4 (secure to prevent falling) & App. A (Cylinder Nesting); and
- A hydrogen cylinder in the Chemical Storage Area that was connected to analytical equipment was not grounded, which is not in accordance with Nat'l Fire Prot. Ass'n, "Standard 55: Compressed Gases and Cryogenic Fluids Code" § 11.2.7 (2013) and Am. Soc'y of Mech. Eng'rs, "Standard B31.12: Hydrogen Piping and Pipelines" § GR-5.2.4 (2012).

- The ventilation fan in Batching Room #1 was only activated during mixing and was blocked by a partially closed wooden door, which is not in accordance with Am. Inst. of Chem. Eng'rs, Ctr. for Chem. Process Safety, "Guidelines for Safe Warehousing of Chemicals" § 6.6.2 (1998) [hereinafter "AiChE CCPS Guidelines for Safe Warehousing of Chemicals"] (discussing types of ventilation systems to "control the buildup of flammable gases or vapor" and describing the need to "ensure that the airflow either sweeps across the floor or ceiling continuously and adequate outside make-up air is provided").
- Pipe labeling in Batching Room #1 was inadequate and was not in accordance with Am. Soc'y of Mech. Eng'rs, "Standard A13.1: Scheme for the Identification of Piping Systems" (2007).
- Production tanks 6697 and 6650 in Batching Room #1 were not properly supported, in that the tanks were resting on several cinderblocks with spaces between them, which is not in accordance with the manufacturer's warning label directing to "support bottom of tank firmly and completely" (without any documentation that this is sufficiently safe).
- Inadequate segregation of incompatible materials in the Chemical Storage Area, where acids were stored with bases and where nitric acid was stored near other acids in the corrosives cabinet, which was not in accordance with AiChE CCPS Guidelines for Safe Warehousing of Chemicals § 2.6;
- Inadequate secondary containment in the following areas, which was not in accordance with AiChE CCPS Guidelines for Safe Warehousing of Chemicals § 6.4 and Nat'l Fire Prot. Ass'n, "Standard 1: Fire Code" § 60.5.1.3.2 (2012) (regarding controlling and mitigating unauthorized releases):
    - Tanks and materials in Batching Room #1;
    - Three (3) one-gallon glass containers on top of the flammables cabinet in the Chemical Storage area; and

- Braided hoses containing paracetic acid mixture running across the floor from Batching Room #1 to the Pouring Area.

Please note that this list may not represent all violations at the Alden Medical facility, and it does not address whether Alden Medical is in compliance with the General Duty Clause obligations to perform a hazard review of the system using appropriate hazard assessment techniques and to take steps needed to minimize the consequences of any releases that may occur, including by implementing a comprehensive emergency response plan.

Notice is hereby given that Alden Medical failed to meet the requirements of Section 312 of EPCRA and Section 112(r) of the CAA cited above. Within 30 days of receipt of this Notice, please submit a description of actions taken to address the violations listed above. Section 114(a)(1) of the CAA, 42 U.S.C. § 7414(a)(1), gives EPA the authority to require a company to submit such information as EPA may reasonably require to determine its compliance with the CAA.

The information should be sent to:

Leonard B. Wallace IV, Enforcement Officer
U.S. Environmental Protection Agency
Office of Environmental Stewardship
RCRA, EPCRA and Federal Programs Unit
Mail Code OES 05-1
5 Post Office Square, Suite 100
Boston, MA 02109-3912

You may, if you desire, assert a business confidentiality claim covering part or all of the information requested, in the manner described by 40 C.F.R. § 2.203(b). You should read the above-cited regulations carefully before asserting a business confidentiality claim, since certain categories of information are not properly the subject of such a claim. If no such claim accompanies the information when it is received by EPA, the information may be made available to the public by EPA without further notice to you.

Failure to correct the violations or submit the requested information may subject Alden Medical to further federal enforcement action, including the assessment of penalties.

If you have any questions concerning this Notice of Noncompliance or regarding Section 312 of EPCRA or Section 112(r) of the CAA, please contact Len Wallace at (617) 918-1835.

Sincerely,

Susan Studlien

Susan Studlien, Director
Office of Environmental Stewardship

cc: Len Wallace, EPA Region I